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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/534,694	01/17/2006	Irina A Buhimschi	035394-0295	6784
22428	7590	08/10/2007	EXAMINER	
FOLEY AND LARDNER LLP			VENCI, DAVID J	
SUITE 500			ART UNIT	PAPER NUMBER
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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/534,694	BUHIMSCHI ET AL.	
	Examiner	Art Unit	
	David J. Venci	1641	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) Responsive to communication(s) filed on May 15, 2007.
- 2a) This action is FINAL. 2b) This action is non-final.
- 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) Claim(s) 61-65,67,68,77,82,90 and 91 is/are pending in the application.
- 4a) Of the above claim(s) 77,82,90 and 91 is/are withdrawn from consideration.
- 5) Claim(s) _____ is/are allowed.
- 6) Claim(s) 61-65,67 and 68 is/are rejected.
- 7) Claim(s) 65 is/are objected to.
- 8) Claim(s) 61-65,67,68,77,82,90 and 91 are subject to restriction and/or election requirement.

Application Papers

- 9) The specification is objected to by the Examiner.
- 10) The drawing(s) filed on May 13, 2005 is/are: a) accepted or b) objected to by the Examiner.
 Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
 Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
 - a) All b) Some * c) None of:
 1. Certified copies of the priority documents have been received.
 2. Certified copies of the priority documents have been received in Application No. _____.
 3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date <u>01/10/2007</u> | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Election/Restrictions

Examiner acknowledges Applicants' election with traverse of Invention I, claims 61-65, 67 and 68. Applicants traverse on the grounds that Cole *et al.* do not teach or suggest diagnosing intra-amniotic inflammation by testing for HNP-1, HNP-2, calgranulin A and calgranulin C.

Applicants' argument has been carefully considered but is not persuasive. Cole *et al.* appear to describe each and every element of kit claim 61 for the reasons set forth in the instant and prior Office Action. Preamble language or language describing kit instructions (e.g., the paper kind) describing Applicants' intended use of the claimed invention do not patentably distinguish Applicants' claimed invention from Cole *et al.* because the language does not result in a structural difference between the claimed invention and the teachings of Cole *et al.*

However, as indicated in the prior Office Action, Examiner will reconsider withdrawing the instant restriction requirement upon indication of allowable subject matter.

Claims 77, 82, 90 and 91 are drawn to non-elected Inventions. Accordingly, claims 77, 82, 90 and 91 are withdrawn from further consideration pursuant to 37 CFR 1.142(b), there being no allowable generic or linking claim.

Currently, claims 61-65, 67 and 68 are under examination.

Specification

The disclosure is objected to because of the following informalities:

In paragraph [0021], first sentence, the phrase "These two pools" lacks basis in previous sentences.

In paragraph [0021], first sentence, a left parenthesis (*i.e.*, a "(") appears to be missing from somewhere.

In paragraph [0039], second sentence, the identity of one or more objects referenced by the phrase "ANN" is not clear.

In Table 1, in the column labeled "PT-CRL 'non-diseased'", the recited "3/12" and "2/15" patient numbers are indefinite in view of " $n = 17$ ". The number of "PT-CRL 'non-diseased'" patients is not clear.

In Table 1, in the column labeled "+AFC +WBC 'diseased'", the recited "3/11" and "8/11" patient numbers are indefinite in view of " $n = 21$ ". The number of "+AFC +WBC 'diseased'" patients is not clear.

In Table 1, in the column labeled "-AFC +WBC", the recited "3/5" and "0/6" patient numbers are indefinite in view of " $n = 7$ ". The number of "-AFC +WBC" patients is not clear.

In Table 1, in the column labeled "+AFC -WBC", the recited "3/7" and "5/3" patient numbers are indefinite in view of " $n = 8$ ". The number of "+AFC -WBC" patients is not clear.

Art Unit: 1641

In Table 1, in the column labeled "-AFC -WBC", the recited "6/13" and "8/16" patient numbers are indefinite in view of "n = 24". The number of "-AFC -WBC" patients is not clear.

In paragraph [0052], first sentence, the identity of one or more objects referenced by the phrase "ID-SDS-PAGE" is not clear. (emphasis added)

In paragraph [0056], first sentence, the synthetic/commercial origin of "PS20 array" is not clear. Whether "PS20" references a CIPHERGEN trademark is not clear.

In paragraph [0062], first sentence, the phrase "the intermingled spots" lacks basis in previous sentences.

In paragraph [0070], the sixth sentence is grammatically awkward.

Appropriate correction is required.

Drawings

Corrected drawing sheets in compliance with 37 CFR 1.121(d) are required in reply to the Office action to avoid abandonment of the application. Any amended replacement drawing sheet should include all of the figures appearing on the immediate prior version of the sheet, even if only one figure is being amended. The figure or figure number of an amended drawing should not be labeled as "amended." If a drawing figure is to be canceled, the appropriate figure must be removed from the replacement sheet, and where necessary, the remaining figures must be renumbered and appropriate changes made to the brief description of the several views of the drawings for consistency. Additional replacement sheets may be necessary to show the renumbering of the remaining figures. Each drawing sheet submitted after the filing date of an application must be labeled in the top margin as either "Replacement Sheet" or "New Sheet" pursuant to 37 CFR 1.121(d). If the changes are not accepted by the examiner, the applicant will be notified and informed of any required corrective action in the next Office action. The objection to the drawings will not be held in abeyance.

The drawings are objected to because, in Fig. 1, the women labeled "non-diseased' (PT-CRL)" are also labeled as having "intraamniotic inflammation". Whether/how "non-diseased" women simultaneously

Art Unit: 1641

have "intraamniotic inflammation" is not clear. Whether the women labeled "non-diseased" (PT-CRL) in Fig. 1 satisfy the specification definition of "intra-amniotic inflammation" of amniotic fluid WBC count > 100 cells/mm³ (see specification paragraph [0059]) is not clear.

Correction is required.

Claim Objections

Claim 65 is objected to under 37 CFR 1.75(c), as being of improper dependent form for failing to further limit the subject matter of base claims 61 and 64. Specifically, language in claim 65 further limiting Applicants' intended use of the claimed invention does not appear to further limit the subject matter of base claims 61 and 64 because intended use limitations do not materially structurally alter any object recited in base claims 61 and 64. Applicants are required to cancel the claim, amend the claim into proper dependent form, or rewrite the claim in independent form.

Art Unit: 1641

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claim 65 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

In claim 65, the phrase "instructions specify" is indefinite. Whether/how inanimate "instructions" are capable of performing "specify" or "specifying" is not clear. The identity of one or more objects or steps, if any, necessary for "instructions" to perform "specify" or "specifying" is not clear.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 61, 64 and 65 are rejected under 35 U.S.C. 102(b) as being anticipated by Cole *et al.*, 504 FEBS LETTERS 5 (2001).

Cole *et al.* describe absorbents (see e.g., p. 5, right column, 2. MATERIALS AND METHODS, 2.1 *Isolation and purification of antimicrobial peptides from human nasal secretions*, "nasal secretions", "vacuum", "catheter tip", "strong cation-exchange HPLC", "Vydac 218TP C18", "MALDI-TOF") for HNP-1, HNP-2 (see e.g., p. 5, right column, line 1 and note 9), calgranulin A and calgranulin C (see e.g., p. 5, right column, first full paragraph), and instructions (see e.g., p. 5, top right corner, "FEBS Letters 504 (2001) 5-10", bottom left corner, "Corresponding author").

Preamble language or language describing kit instructions (e.g., the paper kind) describing Applicants' intended use of the claimed invention do not patentably distinguish Applicants' claimed invention from Cole *et al.* because the language does not result in a structural difference between the claimed invention and the teachings of Cole *et al.*

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 62, 63, 67 and 68 are rejected under 35 U.S.C. 103(a) as being unpatentable^{1,2} over Cole et al., 504 FEBS LETTERS 5 (2001), in view of Hutchens & Yip (US 6,225,047).

Cole et al. describe kit components as substantially described *supra*.

Cole et al. do not describe antibody adsorbents (*i.e.*, claim 62), enzyme-antibody conjugates (*i.e.*, claim 63), or hydrophobic C9/C16 adsorbents (*i.e.*, claims 67 and 68).

However, Hutchens & Yip describe antibody adsorbents (see col. 29, line 55, "immobilized antibodies"), enzyme-antibody conjugates (see paragraph bridging col. 15-16, "enzymes (*e.g.*, as commonly used in an ELISA)'), or hydrophobic C9/C16 adsorbents (see col. 26, lines 64-65, "C₁-C₁₈ aliphatic hydrocarbons") for use on MALDI/SELDI mass spectrometry probes.

It would have been obvious to a person of ordinary skill to substitute Cole's various kit components with the adsorbents and conjugates of Hutchens & Yip because Hutchens & Yip provide a single, integrated operating system coupling both adsorption chromatography with desorption spectrometry (see col. 3,

¹ In the Supreme Court decision *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), the Court set forth factual inquiries establishing a background for determining obviousness under 35 U.S.C. 103(a). The factual inquiries include: (1) determining the scope and contents of the prior art; (2) ascertaining the differences between the prior art and the claims at issue; (3) resolving the level of ordinary skill in the pertinent art; and (4) considering objective evidence indicating obviousness or nonobviousness.

² The lack of objective evidence of nonobviousness in the instant application does not suggest "the level of ordinary skill in the pertinent art" is high.

Art Unit: 1641

lines 32-35). Furthermore, Hutchens & Yip provide a system capable of parallel processing of multiple analytes (see col. 3, lines 40-44).

Art Unit: 1641

Response to Arguments

Claim Rejections - 35 USC § 112

In prior Office Action, claims 77 and 82 were rejected under 35 U.S.C. 112, second paragraph, as being indefinite for various reasons.

In the instant Office Action, claims 77 and 82 are withdrawn from further consideration pursuant to 37 CFR 1.142(b) for being drawn to non-elected Inventions. Applicants' argumentation with respect to claims 77 and 82 will be considered upon rejoinder of Inventions II and III (see Requirement for Restriction/Election, dated April 17, 2007).

Prior Art Claim Rejections

In prior Office Action, claim 77 was rejected under 35 U.S.C. 102(b) as being anticipated by Hitomi *et al.* (US 5,976,832). Claim 82 was rejected under 35 U.S.C. 103(a) as being unpatentable in view of Hitomi *et al.* (US 5,976,832) and Krone *et al.*, 244 ANAL. BIOCHEM. 124 (1997). Claim 90 was rejected under 35 U.S.C. 103(a) as being unpatentable in view of Hitomi *et al.* (US 5,976,832), Krone *et al.*, 244 ANAL. BIOCHEM. 124 (1997), Parker (US 4,020,006) and Woodruff (US 5,545,616).

In the instant Office Action, claims 77, 82 and 90 are withdrawn from further consideration pursuant to 37 CFR 1.142(b) for being drawn to non-elected Inventions. Applicants' argumentation with respect to claims 77, 82 and 90 will be considered upon rejoinder of Inventions II and III (see Requirement for Restriction/Election, dated April 17, 2007).

In prior Office Action, claims 61-63 were rejected under 35 U.S.C. 103(a) as being unpatentable in view of Hitomi *et al.* (US 5,976,832) and Burke & Alexander (US 5,965,354). Claims 64, 65 and 67 were rejected under 35 U.S.C. 103(a) as being unpatentable in view of Hitomi *et al.* (US 5,976,832), Burke & Alexander

Art Unit: 1641

(US 5,965,354) and Krone *et al.*, 244 ANAL. BIOCHEM. 124 (1997). Claim 68 was rejected under 35 U.S.C. 103(a) as being unpatentable in view of Hitomi *et al.* (US 5,976,832), Burke & Alexander (US 5,965,354), Krone *et al.*, 244 ANAL. BIOCHEM. 124 (1997), and Pham (US 2002/0060290).

In response, Applicants amend independent claim 61 to require adsorbents that bind to "HNP-1" and "HNP-2".

Applicants' amendment is sufficient to overcome these rejections. Accordingly, these rejections are withdrawn.

Art Unit: 1641

Conclusion

No claims are allowable at this time.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to David J. Venci whose telephone number is 571-272-2879. The examiner can normally be reached on 08:00 - 16:30 (EST). If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Long Le can be reached on 571-272-0823. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

David J Venci
Assistant Examiner
Art Unit 1641

djv

Long V. Le 01/05/07
LONG V. LE
SUPERVISORY PATENT EXAMINER
TECHNOLOGY CENTER 1600